

### Remarks

The November 19, 2003 Official Action has been carefully considered. In view of the present amendment and these remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three (3) months was set in the November 19, 2003 Official Action. The initial due date for response, therefore, was February 19, 2004. A petition for a three (3) month extension of the response period is presented with this RCE and submission under 37 C.F.R. §1.114, which are being filed before the expiration of the three (3) month extension period.

Claim 64-67, 71, 75, 76, 95, 102 and 103 (hereinafter "the claims under consideration") were rejected on various grounds in the November 19, 2003 Official Action, and the remaining claims, namely, claims 42-53, 72, 73, 80 and 90 were withdrawn from consideration as directed to non-elected subject matter.

Regarding the specific grounds of rejection set forth in the November 19, 2003 Official Action, the claims under consideration were rejected as failing to satisfy the written description of 35 U.S.C. §112, first paragraph. The examiner contends in this regard that there is no support in the specification as originally filed for the recitation of "substantially free of sequences of native human Tek protein which are not part of said at least one MHC-binding epitope of

Tek" in claim 64. Also in this connection, the examiner asserts that the written description provided in the specification is not commensurate with the scope of the claims under consideration, because the specification only provides the identity of peptides that bind a single class I allele (HLA-A2) and stimulate T-cell proliferation, whereas the claims under consideration encompass immunogenic MHC-binding Tek peptides derived from human Tek of Figure 1, and the art purportedly recognizes that there are hundreds of MHC class I and class II alleles in humans wherein such molecules bind different and largely non-overlapping sets of peptides derived from the same protein.

The claims under consideration have also been rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite, in that claims 64, 67 and 71 depend from non-elected claim 42, and claim 64 includes the allegedly unclear terminology "substantially free of sequences of native human Tek protein which are not part of said at least one MHC-binding epitope of Tek" and "consists essentially of", the latter expression being referred to in the specification as including "little in the way of other sequences of the native Tek protein".

The claims under consideration were further rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. patent No. 5,681,714 to Breitman et al., as evidenced by Rammensee et al.

The foregoing rejections constitute all of the grounds set forth in the November 19, 2003 Official Action for refusing

the present application.

In accordance with the present amendment, all of the claims indicated in the November 19, 2003 Official Action as pending in this application have been cancelled, and new claims 104-132 are presented for consideration by the examiner. These new claims are in keeping with the election made by applicants in reply to the restriction requirement set forth in the Official Action dated February 15, 2002.

Support for the subject matter of new claims 104-132 is provided in the present specification, as indicated in the following table:

Claim	Support in specification
104	Page 4, lines 30-33; Page 5, lines 3-7; Page 6, lines 14-19; and Pages 31-36 (and Tables 1-4)
105-106	Page 33, lines 22-26
107	Page 35, lines 3-6
108-110 112-114	Page 4, lines 30-33
111	Page 6, lines 19-22; and Page 35, line 21-page 36, line 23
115 and 116	Original claims 13 and 14
117, 118, 127 and 128	Original claim 26
119, 120, 129 and 130	Original claim 27
121 and 122	Original claim 28
123-126, 131 and 132	Original claim 40

No new matter is being introduced into this application by reason of any of the claims presented herewith.

The various grounds of rejection set forth in the November 19, 2003 Official Action are inapplicable to newly presented claims 104-132. These grounds of rejection are, therefore, respectfully traversed.

Considering first the rejection based on alleged inadequate written description, the relevant inquiry in determining compliance with the written description requirement of 35 U.S.C. §112, first paragraph, is whether the originally filed specification reasonably conveys to a person having ordinary skill in the art that applicants had possession of the claimed subject matter. In re Kaslow, 217 USPQ 1089 (Fed.Cir. 1983).

Furthermore, the examiner has the initial burden of presenting evidence or reasons why a person of ordinary skill in the art would not recognize an applicants' specification a description of the invention defined by the claims. Ex parte Sorenson, 3 USPQ 2<sup>nd</sup> 1462 (Bd. Pat. App. 1987).

The inadequate written description rejections cannot be maintained with respect to new claims 104-132. First of all, the terminology that gave rise to these rejections is omitted from new claims 104-132. More to the point, it would be evident to a person having ordinary skill in the art, from the various specification passages listed in the foregoing table, that applicants were in possession of the claimed subject matter. In

short, applicants' specification and claims achieve the kind of specificity held to be required in Fiers v. Revel, 25 USPQ 2<sup>nd</sup> 1601 (Fed.Cir. 1993), by reciting the amino acid sequence of the epitopes encoded by the claimed nucleic acid molecule.

For the above-stated reasons it is clear that the inadequate written description rejection set forth in the November 19, 2003 Official Action cannot be maintained with respect to new claims 104-132.

Turning to the rejection based on alleged indefiniteness, this rejection is likewise inapplicable to new claims 104-132. Any indefiniteness or lack of clarity that may have been engendered by improper claim dependency or claim terminology appearing in claim 64 which the examiner considers objectionable has been eliminated from new claims 104-132.

The terminology employed in new claims 104-132 is such that any person of ordinary skill in the art, having these claims and applicants' specification before him or her, would be apprised to a reasonable degree of certainty as to the exact subject matter encompassed thereby. Nothing more is required under 35 U.S.C. §112, second paragraph.

For the above-stated reasons, the indefiniteness rejection under 35 U.S.C. §112, second paragraph set forth in the November 19, 2003 Official Action cannot be maintained with respect to new claims 104-132.

As for the 35 U.S.C. §102(b) rejection based on Breitman et al. as evidenced by Rammensee et al., the encoded

polypeptides called for in new claims 104-132 are distinguishable from the fragments of Tek disclosed in Breitman et al., because none of the fragments of Breitman et al. meets both the requirements of (1) comprising one or more of the epitopes recited in new claim 104 and (2) comprising less than 50% of the amino acid sequence of native Tek as shown in Figure 1 (SEQ ID NO: 1).

Breitman et al. provides a generic description of peptide fragments, and the law is well settled that such generic disclosure does not anticipate claims drawn to specific subject matter.

Breitman et al. also discloses certain specific fragments that do not fall within the claims presented herewith. The specific fragments disclosed by Breitman et al. are (1) the C-terminal 43 amino acids of Tek (Column 34, 3<sup>rd</sup> complete paragraph, as cited by the examiner) and (2) the extracellular domain, consisting of amino acids 19-744, disclosed in the context of a fusion protein (Column 21, 7<sup>th</sup> complete paragraph). The C-terminal 43 amino acids lack any of the epitopes recited in claim 104, and the extracellular domain comprises more than 50% of the amino acid sequence of native Tek (19-744=725 amino acids; SEQ ID NO: 1 is 1124 amino acids in length; 725 is 64.5% of 1124, i.e. insignificantly greater than 50%). Accordingly, new claims 104-132 are patentably distinguishable over Breitman et al.

In view of the clear differences between the subject

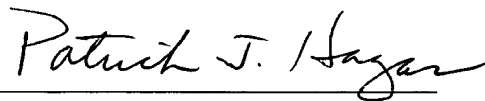
matter of claims 104-132 and Breitman et al., as noted above, the examiner's continued reliance on Rammensee would be misplaced, considering that this reference is being cited for its disclosure of the anchor residues for HLA-B\*2705, which purportedly demonstrates that the C-terminal 43 amino acids of Tek would inherently comprise an MHC-binding epitope. New claims 104-132 call for specific epitopes of Tek protein that are not found in the C-terminal 43 amino acids of Tek.

For the foregoing reasons, the anticipation rejection based on Breitman et al. as evidenced by Rammensee cannot reasonably be maintained with respect to new claims 104-132.

In view of the present amendment and the foregoing remarks it is respectfully requested that all of the rejections set forth in the November 19, 2003 Official Action be withdrawn and that this application be passed to issue, and such action is earnestly solicited.

Respectfully submitted,

DANN, DORFMAN, HERRELL and SKILLMAN

A handwritten signature in cursive script, reading "Patrick J. Hagan", is written over a horizontal line.

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Enclosures: